

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

IN RE JUBLIA

: Case No. 3:18-cv-13635 (BRM) (LHG)

:

:

OPINION

:

MARTINOTTI, DISTRICT JUDGE

Before this Court are the applications by Plaintiffs Valeant Pharmaceuticals North America, LLC, Valeant Pharmaceuticals Ireland Ltd., Dow Pharmaceutical Sciences, Inc., and Kaken Pharmaceutical Co. Ltd (collectively, “Plaintiffs”) Defendants Zydus Pharmaceuticals (USA) Inc., Zydus Worldwide DMCC, and Cadila Healthcare Limited d/b/a Zydus Cadila (collectively, “Defendants”) for claim construction to resolve disputes over one claim term: “nail.” (ECF Nos. 139-40 & 146-47.)

This Court has examined the disputes over the construction of these claim terms and, for the reasons set forth in this Opinion, this Court defines the disputed claim term “nail” to mean “nail plate.”

I. BACKGROUND

A. Factual Background

This case arises out of an action for infringement of Plaintiffs’ patents¹ by Defendants’ filing of an Abbreviated New Drug Application (“ANDA”) seeking U.S. Food and Drug

¹ The patents-in-suit are United States Patent Nos. 7,214,506 (“the ’506 patent”), 8,039,494 (“the ’494 patent”), 8,486,978 (“the ’978 patent”), 9,302,009 (“the ’009 patent”), 9,566,272 (“the ’272 patent”), 9,662,394 (“the ’394 patent”), 9,861,698 (“the ’698 patent”) and 9,877,955 (“the ’955 patent”) arising under the United States patent laws, Title 35, U.S.C. § 100 *et seq.*, including 35 U.S.C. §§ 271 & 281 (collectively “the patents-in-suit”).

Administration (“FDA”) approval to market a generic version of Plaintiffs’ product Jublia®—an efinaconazole topical solution, 10%. (ECF No. 1 ¶ 9.)

Between May 8, 2007, and January 30, 2018, the United States Patent and Trademark Office (“PTO”) issued the patents-in-suit, which describe various methods and pharmaceutical compositions for treating onychomycosis. (*See id.* ¶¶ 21-28.) Onychomycosis is an infection of the nail unit caused by fungi. (*See id.* Ex. 1.) The parties dispute the proper construction of a single term, “nail,” used in eight of the nine patents-in-suit.² The chart below sets forth the parties’ proposed constructions.

Claim Language	Asserted Claims	Plaintiffs’ Proposed Construction	Defendants’ Proposed Construction
“nail”	’494 patent claim 1; ’978 patent claims 1, 2, 21, 41; ’009 patent claim 1; ’272 patent claim 1; ’698 patent claims 2, 11; ’955 patent claims 1, 12, 14; ’444 patent claims 2, 9; ’394 patent claim 11	“nail plate”	Plain and ordinary meaning, <i>i.e.</i> , “nail unit”

B. Procedural History

On September 6, 2018, Plaintiffs filed a Complaint asserting claims of infringement against Defendants. (ECF No. 1.) On March 5, 2019, Defendants filed an Answer to the Complaint along with counterclaims asserting the noninfringement and invalidity of the patents-in-suit. (ECF No. 20.)

² The meaning of the term “nail” in the ’506 patent is not at issue. Therefore, the Court will only analyze the meaning of the term as it is used in the remaining eight patents. (*See* ECF No. 140 at 6 n.2.)

On January 8, 2020, both Plaintiffs and Defendants filed their opening *Markman* briefs. (ECF Nos. 139 & 140.) On March 9, 2020, both Plaintiffs and Defendants filed their *Markman* reply briefs. (ECF Nos. 146 & 147.)³

II. LEGAL STANDARD

Claims define the scope of the inventor's right to exclude. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005). Claim construction determines the correct claim scope and is a determination reserved exclusively for the court as a matter of law. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 978-79 (Fed. Cir. 1995) (*en banc*). Indeed, the court can only interpret claims and “can neither broaden nor narrow claims to give the patentee something different than what it has set forth” in the specification. *E.I. Du Pont de Nemours v. Phillips Petroleum Co.*, 849 F.2d 1430, 1433 (Fed. Cir. 1998). A court's determination “of patent infringement requires a two-step process: first, the court determines the meaning of the disputed claim terms, then the accused device is compared to the claims as construed to determine infringement.” *Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 804 (Fed. Cir. 2007).

This interpretive analysis begins with the language of the claims, which is to be read and understood as it would be by a person of ordinary skill in the art. *Dow Chem. Co. v. Sumitomo Chem Co.*, 257 F.3d 1364, 1372 (Fed. Cir. 2001); *see also Markman v. Westview Instruments*, 52 F.3d 967, 986 (Fed. Cir. 1995) (*en banc*), *aff'd*, *Markman*, 517 U.S. 370 (holding that “[t]he focus [in construing disputed terms in claim language] is on the objective test of what one of ordinary skill in the art at the time of invention would have understood the terms to mean”); *Phillips*, 415

³ The Court had originally scheduled a *Markman* hearing for March 23, 2020. However, as a result of the COVID-19 pandemic, federal and state declarations of a state of emergency, and associated shelter in place and social distancing edicts, the parties waived the hearing and the matter was decided on the submissions.

F.3d at 1312-13. In construing the claims, the court may examine both intrinsic evidence (e.g., the patent, its claims, the specification, and the prosecution history) and extrinsic evidence (e.g., expert reports and testimony). *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1309 (Fed. Cir. 1999).

The analysis of claim language begins with determining the “ordinary and customary meaning of a claim term[, which] is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” *Phillips*, 415 F.3d at 1313. Further, the language should not be read solely in the context of the claim under review; instead, it should be analyzed “in the context of the entire patent” and with an understanding of how that language is used in the field from which the patent comes. *Id.* In conducting this review, a different interpretation is placed on a term located in an independent claim than on those located in dependent claims, and it is understood that each claim covers different subject matter. *Saunders Grp., Inc. v. Comfortrac, Inc.*, 492 F.3d 1326, 1331 (Fed. Cir. 2007) (quoting *Phillips*, 415 F.3d at 1315 (holding that the “presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim”))).

In reviewing the language of a patent, “the court starts the decision-making process by reviewing the same resources as would [a person of ordinary skill in the art in question], viz., the patent specifications and the prosecution history.” *Phillips*, 415 F.3d at 1313 (quoting *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477 (Fed. Cir. 1998)). When “the ordinary meaning of claim language as understood by a person of skill in the art [is] readily apparent,” understanding claim construction “involves little more than the application of the widely accepted

meaning of commonly understood words.” *Phillips*, 415 F.3d at 1314. “In such circumstances, general purpose dictionaries may be helpful” to explain the terms used. *Id.*

Often times, however, the ordinary meaning of the claim language is not readily apparent, and in such circumstances, courts look to “those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean.” *Id.* Those sources may include “the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.” *Id.* Furthermore, claims must be read in view of the claim specification, which is of seminal importance in providing framework for understanding the claim language. As the Federal Circuit in *Markman* explained:

The specification contains a written description of the invention that must enable one of ordinary skill in the art to make and use the invention. For claim construction purposes, the description may act as a sort of dictionary, which explains the invention and may define terms used in the claims. As we have often stated, a patentee is free to use his [or her] own lexicographer. The caveat is that any special definition given to a word must be clearly defined in the specification. The written description part of the specification itself does not delimit the right to exclude. That is the function and the purpose of the claims.

Markman, 52 F.3d at 979-80.

This Court’s reliance on the specification is appropriate given the Patent and Trademark Office’s rules requiring “that application claims must ‘conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent bases in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description.’” *Phillips*, 415 F.3d at 1316-17 (quoting 37 C.F.R. § 1.75(d)(1)). During this analysis, however, courts should not “import limitations from the

specifications into the claims.” *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1370 (Fed. Cir. 2008) (quoting *CollegeNet, Inc. v. ApplyYourself, Inc.*, 418 F.3d 1225, 1231 (Fed. Cir. 2005)).

The patent’s prosecution history is also of “primary significance in understanding the claims.” *Markman*, 52 F.3d at 980. “The prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.” *Phillips*, 415 F.3d at 1317. Further, the prosecution history is also relevant to determining whether the patentee disclaimed or disavowed the subject matter, thereby narrowing the scope of the claim terms. *Seachange Int’l, Inc. v. C-Cor Inc.*, 413 F.3d 1361, 1372-73 (Fed. Cir. 2005).⁴

In addition to intrinsic evidence, a court may also rely on extrinsic evidence in interpreting a claim. *Phillips*, 415 F.3d at 1317. Extrinsic evidence consists of “all evidence external to the

⁴ “[I]n certain cases, the specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor.” *Ventana Med. Sys., Inc. v. Biogenex Labs., Inc.*, 473 F.3d 1173, 1181 (Fed. Cir. 2006) (quoting *Phillips*, 415 F.3d at 1316) (internal citations omitted). In such cases, the Federal Circuit interprets the claim more narrowly than it otherwise would in order to give effect to the patentee’s intent to disavow a broader claim scope. *Ventana*, 473 F.3d at 1181 (citing *Honeywell Int’l, Inc. v. ITT Indus., Inc.*, 452 F.3d 1312, 1319-20 (Fed. Cir. 2006); *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1342-44 (Fed. Cir. 2001)). However, pointing solely to “general statements by the [patentee] indicating that the invention is intended to improve upon prior art” will not demonstrate that the patentee intended to “disclaim every feature of every prior art device discussed in the ‘BACKGROUND ART’ section of the patent.” *Ventana*, 473 F.3d at 1181; see also *Thorner v. Sony Computer Ent. Am. LLC*, 669 F.3d 1362, 1366 (Fed. Cir. 2012) (“Mere criticism of a particular embodiment encompassed in the plain meaning of a claim term is not sufficient to rise to the level of clear disavowal.”) Moreover, the Federal Circuit has found it “particularly important not to limit claim scope based on statements made during prosecution ‘[a]bsent a clear disavowal or contrary definition.’” *Digital Vending Servs. Int’l, LLC v. Univ. of Phoenix, Inc.*, 672 F.3d 1270, 1273 (Fed. Cir. 2012) (citing *August Tech. Corp. v. Camtek, Ltd.*, 655 F.3d 1278, 1286 (Fed. Cir. 2011) (quoting *Home Diagnostics, Inc. v. LifeScan, Inc.*, 381 F.3d 1352, 1358 (Fed. Cir. 2004))). The reason for such a stringent rule is “because the prosecution history represents an ongoing negotiation between the PTO and the application,” and “it often lacks the clarity of the specification and thus is less useful for claim construction purposes.” *Digital Vending*, 672 F.3d at 1273 (quoting *Phillips*, 415 F.3d at 1317).

patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” *Id.* (citations omitted). However, while extrinsic evidence “can shed useful light on the relevant art,” it is “less significant than the intrinsic record in determining the legally operative meaning of claim language.” *Id.* Extrinsic evidence should be “considered in the context of intrinsic evidence,” as there are flaws inherent in the exclusive reliance on extrinsic evidence, including, *inter alia*, biases, inadvertent alterations of meanings, and erroneous contextual translations. *Id.* at 1318-19. Furthermore, extrinsic evidence should not be relied upon where “an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term.” *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996).

III. DECISION

This Court addresses the interpretation of the one disputed term: “nail.”

A. The Meaning of “nail”

Plaintiffs propose that “nail” be construed to mean “nail plate” (ECF No. 140 at 18), whereas Defendants propose that “nail” be construed to have its plain and ordinary meaning, *i.e.*, “nail unit.” (ECF No. 139 at 12.)

Foremost, the parties do not dispute that “nail unit” has an ordinary meaning which includes, among other components, the nail plate and nail bed. The nail plate is a rigid outer portion, and the nail bed is the dermis directly beneath the nail plate. (*See generally*, ECF Nos. 139 & 140.) However, the present issue is whether the term “nail” as asserted in the patents-in-suit refers to merely the nail plate or encompasses the entire nail unit—inclusive of the nail plate, nail bed, and other structures. In construing the claims, the Court first looks to the words of the claims themselves. *See Vitronics*, 90 F.3d at 1582; *Sandisk v. Memorex Prods.*, 415 F.3d 1278, 1283-84 (Fed. Cir. 2005) (“Claim construction begins with the language of the asserted claims.”)

Plaintiffs first contend “nail” means “nail plate” because the claims consistently use the phrase “treatment of a disorder of the nail or nail bed.”⁵ (ECF No. 140 at 19-20.) Specifically, Plaintiffs argue the use of the word “or” indicates the “nail” is distinct from the “nail bed.” (*Id.* at 20.) Because the nail bed is part of the nail unit, Plaintiffs argue, Defendants’ proposed construction would render the phrase “or nail bed” superfluous and redundant. (*Id.*)

However, Defendants contend their construction would not make “or nail bed” superfluous because a person of ordinary skill in the art (“POSA”) would understand a topical fungal treatment such as Jublia could be applied to either: 1) the nail unit in its entirety; or 2) the nail bed after removal of the nail plate. (ECF No. 147 at 10.)

In support of its argument, Defendants focus on language in the specifications of the patents-in-suit. The specifications note:

Because of the difficulty in obtaining clinically effective concentrations of medication to the nail bed by topical application of a pharmaceutical composition to the affected nail, nail disorders, such as onychomycosis, are typically treated with systemic medications or with topical medications following **removal of the nail**. . . . Antifungal compounds, such as miconazole and ketoconazole, have been demonstrated to be effective in topically treating onychomycosis after **nail removal**.

(ECF No. 139 at 13-14 (citing ECF No. 140-3 at 7) (emphasis added).)

In relation to the above passage, Defendants contemplate a scenario “where a patient has had the nail plate component of the nail removed.” (ECF No. 139 at 14.) Therefore, in Defendants’ reading of the specifications, “nail removal” refers to removal of the nail plate, rather than the entire nail unit. Indeed, removal of the entire nail unit to treat fungal infections would be absurd. Moreover, the above language detailing the removal of the nail plate to treat fungal infections

⁵ These include ’978 patent claims 2 and 21, ’494 patent claim 1, ’009 patent claim 1, ’444 patent claim 9, ’698 patent claims 2 and 11, and ’272 patent claim 1.

represents the required treatment method *before* the invention of the patented formulations. The specifications later go on to state:

A significant need remains for a pharmaceutical composition that provides for enhanced penetration of a pharmaceutical agent contained within the composition **into and through a nail and into the nail bed**. Such a composition would be valuable for topically treating conditions affecting the nail or nail bed, such as onychomycosis.

(ECF No. 140-3 at 7 (emphasis added).)

Therefore, while Defendants argue a POSA would understand the removal of the nail plate as a means to treat fungal infections, the specifications expressly dismiss such treatment in favor of one that goes in through a nail and into the nail bed.

Additionally, the specifications provide further support for Plaintiffs proposed construction by describing the properties of the “nail.” The specifications read:

The **nail plate** is thick, hard, and dense, and represents a formidable barrier to drug penetration. Although nail material is similar in various ways to the stratum corneum of the skin, **the nail is composed primarily of hard keratin which is highly disulfide-linked and is approximately 100-fold thicker than stratum corneum**.

(ECF No. 140-3 at 6.)

Defendants contend the use of “nail” above should be construed as “nail unit” because the nail unit is primarily composed of hard keratin. (ECF No. 147 at 17.) However, Defendants have made no showing that the nail unit is “composed primarily of hard keratin which is highly disulfide-linked.” Indeed, these are structural properties specific to the nail plate. Further, Defendants fail to explain how their construction would comport with the phrase “approximately 100-fold thicker than stratum corneum.” Stratum corneum refers to skin, similar to the dermis layer such as the nail bed. However, it would be absurd to say the nail unit is 100-fold thicker than

stratum corneum, as stratum corneum is part of the nail unit. Therefore, the only construction of “nail” that comports with the above portion of the specifications is “nail plate.”

Finally, Defendants contend Plaintiffs’ construction would render claim 11 of the ’394 patent impermissibly narrower than claim 16—a dependent claim. (ECF No. 139 at 17.) Claim 11 considers a “pharmaceutically acceptable formulation that is effectively absorbed in the treatment of the nail.” (*See* ECF No. 139 at 16.) Additionally, dependent claim 16 recites a “method of treating a fungal infection,” which is defined in the ’394 patent as “unwanted growth of a fungus on the skin or nails.” (*Id.*) Therefore, Defendants argue, Plaintiffs’ construction of “nail” as “nail plate” would “exclude the broader method of claim 16 of treating a ‘fungal infection’ affecting more than just the nail plate.” (*Id.* at 17.) The Court finds this interpretation lacks merit.

While correct that claim 16 must be narrower than claim 11, Defendants’ conclusion that “nail” must mean “nail unit” does not follow. Under Plaintiffs’ proposed construction, claim 11 is limited to treatment of the nail plate, and claim 16 further limits claim 11 by defining the infection as fungal. (ECF No. 146 at 10.) Therefore, despite Defendants’ contentions, Plaintiffs’ proposed construction comports with the rules of claim construction.

Accordingly, the Court defines “nail” as “nail plate.”

IV. CONCLUSION

For the reasons set forth above, this Court defines the disputed claim term “nail” to mean “nail plate.” An appropriate order follows.

Date: May 7, 2020

/s/ Brian R. Martinotti
HON. BRIAN R. MARTINOTTI
UNITED STATES DISTRICT JUDGE